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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/621,725	03/21/96	LEHMANN	CASE-02138

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EXAMINER  
SCHWADRON, R

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 09/01/98

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.  
**08/621,725**

Applicant(s)

**Lehmann et al.**

Examiner  
**Ron Schwadron, Ph.D.**

Group Art Unit  
**1644**



☐ Responsive to communication(s) filed on \_\_\_\_\_

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 1, 2, 4-8, and 18 is/are pending in the application.

Of the above, claim(s) 4-8 is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 1, 2, and 18 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

15. Claims 1,2 and 18 are under consideration. Claims 3 and 19 have been cancelled. Claims 1 and 18 have been amended.

## RESPONSE TO APPLICANTS ARGUMENTS

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

17. Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Namikawa et al. in view of Tobin et al. (US Patent 5,674,978) and prior art disclosed in the specification (Alvord et al., Zamvil et al., Kimball). Applicants arguments have been considered and deemed not persuasive.

The claim is drawn to the method of claim 1. Namikawa et al. teach that immunization with MBP in IFA prevents EAE in rats (see page 932, first column, first paragraph). The specification discloses that the art recognizes certain similarities between EAE and human MS (see page 2, first paragraph). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed method because Namikawa et al. teach that immunization with MBP in IFA prevents EAE in rats and the art recognized similarities between EAE and human MS. One of ordinary skill in the art would have been motivated to do the aforementioned because Tobin et al. teach treatment with autoimmune antigens for the treatment of human disease.

Regarding applicants comments in the instant amendment, Namikawa et al. teach that, "Furthermore, immunization of rats by injection of BP in IFA not only prevents subsequent active or passive induction of EAE, but also has been reported to induce cells capable of preventing

active sensitization of recipients.”(page 932, first column, first paragraph). Regarding applicants comments about the safety and efficacy of said treatment, virtually no known pharmaceutical agent currently used in humans is without side effects or is known to possess efficacy in every treated individual. Furthermore, the M.P.E.P. section 2143.02 (page 2100-111, Rev. 3, July 1997) discloses that:

“> OBVIOUSNESS REQUIRES ONLY A REASONABLE EXPECTATION OF SUCCESS

The prior art can be modified or combined to reject claims as prima facie obvious as long as there is a reasonable expectation of success. In re Merck & Co., Inc. , 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986) (Claims directed to a method of treating depression with amitriptyline (or nontoxic salts thereof) were rejected as prima facie obvious over prior art disclosures that amitriptyline is a compound known to possess psychotropic properties and that imipramine is a structurally similar psychotropic compound known to possess antidepressive properties, in view of prior art suggesting the aforementioned compounds would be expected to have similar activity because the structural difference between the compounds involves a known bioisosteric replacement and because a research paper comparing the pharmacological properties of these two compounds suggested clinical testing of amitriptyline as an antidepressant. The court sustained the rejection, finding that the teachings of the prior art provide a sufficient basis for a reasonable expectation of success.); Ex parte Blanc , 13 USPQ2d 1383 (Bd. Pat. App. & Inter. 1989) (Claims were directed to a process of sterilizing a polyolefinic composition with high - energy radiation in the presence of a phenolic polyester antioxidant to inhibit discoloration or degradation of the polyolefin. Appellant argued that it is unpredictable whether a particular antioxidant will solve the problem of discoloration or degradation. However, the Board found that because the prior art taught that appellant's preferred antioxidant is very efficient and provides better results compared with other prior art antioxidants, there would have been a reasonable expectation of success.).”. Regarding applicants comments about Tobin, Namikawa et al. teach that, “Furthermore, immunization of rats by injection of BP in IFA not only prevents subsequent active or passive induction of EAE, but also has been reported to induce cells capable of preventing active sensitization of recipients.”(page 932, first column, first paragraph). Thus, Namikawa et al. teach that immunization with MBP in IFA prevents EAE in rats (see page 932, first column, first paragraph)., while the specification discloses that the art recognizes certain similarities

between EAE and human MS (see page 2, first paragraph).

18. Claims 1,2,18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Namikawa et al. in view of Tobin et al. (US Patent 5,674,978) and prior art disclosed in the specification (Alvord et al., Zamvil et al., Kimball) as applied to claim 1 above, and further in view of Goodwin et al. (US Patent 5,569,585) and Viselli et al. Applicants arguments have been considered and deemed not persuasive.

The claims are drawn to the method of claims 2,18,19. The previous paragraph makes obvious the claimed invention except for the use of the immunoassay recited in the claims. Namikawa et al. teach that after immunization, the response of cells to a T cell mitogen is tested (see Table 3 and page 934, column 1). The response of T cells would have been alternatively measured using art known lymphokine assays, because the art recognizes that activated T cells produce lymphokines in response to antigenic stimulation (see Goodwin et al., see column 10, penultimate paragraph). ELISA assays for T cell cytokines are known in the art as is the membrane recited in claim 2 (see specification, page 8, first paragraph and Goodwin et al., column 10 ). Viselli e al. teach the use of PVDF membranes in immunoassays. It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because the previous rejection makes obvious the claimed invention except for the use of the immunoassay recited in the claims, while Namikawa et al. teach that after immunization, the response of cells to a T cell mitogen is tested and the response of T cells would have been alternatively measured using art known lymphokine assays, because the art recognizes that activated T cells produce lymphokines in response to antigenic stimulation (see Goodwin et al., see column 10, penultimate paragraph) and ELISA assays for T cell cytokines are known in the art. One of ordinary skill in the art would have been motivated to do the aforementioned because Namikawa et al. teach that after immunization, the response of cells to a T cell mitogen is tested and the response of T cells would have been alternatively measured using art known lymphokine assays, because the art recognizes that activated T cells produce lymphokines in response to antigenic stimulation.

Regarding applicants comments in the instant amendment, Viselli e al. teach the use of PVDF membranes in immunoassays.

19. No claim is allowed.

20. Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Papers should be faxed to Group 1600 at (703) 305-3014.

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Ron Schwadron whose telephone number is (703) 308-4680. The examiner can normally be reached Tuesday through Friday from 8:30 to 6:00. The examiner can also be reached on alternative Mondays. A message may be left on the examiners voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 180 receptionist whose telephone number is (703) 308-0196.

RONALD B. SCHWADRON  
PRIMARY EXAMINER  
GROUP 1800 1600



Ron Schwadron, Ph.D.  
Primary Examiner  
Art Unit 1644  
August 31, 1998

Serial No. 08/621725  
Art Unit 1644

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